DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1514d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

July 18, 2001

WL-67-01

James A. Bixby
President and CEO
SeQual Technologies, Inc.
11436 Sorrento Valley Road
San Diego, CA 92121

Dear Mr. Bixby:

During an inspection of your firm located in San Diego, California, on May 15 to June 8, 2001, our investigator determined that your firm manufactures portable oxygen concentrators. Oxygen concentrators are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection disclosed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, and storage are not in conformance with the current Good Manufacturing Practice (cGMP) requirements for the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to control your firm's corrective and preventive actions procedures to ensure that all data from quality data sources are analyzed to identify existing and potential causes of nonconforming product and other quality problems [21 CFR 820.100(a)(1)]. Specifically, our investigation disclosed that approximately fifty nonconforming devices were returned to your company from March 2000 to July 2001 for quality problems and there was no documentation describing any evaluations of the returned goods or their quality problems as they related to your customer complaints and MDR systems or your internal audit activities.

2. Failure to ensure that a process whose results cannot be fully verified by subsequent inspection and testing, has been validated and approved according to established procedures [21 CFR 820.75(a)]. Specifically, your firm has no documented evidence that provides a high degree of assurance that the manufacturing specifications and processing controls used in the automated and software controlled adhesive operations of your manifold and port plate subassemblies of your oxygen concentrators will consistently produce a product meeting its pre-determined specifications and quality attributes (traditionally termed validation).

Additionally, our investigation revealed that your devices are misbranded within the meaning of Section 502(t)(2) of the Act in that your establishment failed to submit information to the Food and Drug Administration as required by the Reports of

Corrections and Removals Regulation, as specified in 21 CFR Part 806. Specifically, your firm failed to report to FDA within 10 days of initiating a correction and removal action involving an overheating and damage issue to your oxygen concentrators. Your firm notified your customers of this corrective action by letter dated June 28, 2000.

We also acknowledge receipt of your letter dated June 15, 2001 to the form FDA 483 that was issued to your firm on June 8, 2001. We have completed our review of your letter and have determined that it does not adequately address our concerns. Specifically, your letter states that your firm will re-examine your procedures and processes and make the necessary changes to prevent recurrence. Your letter does not describe any corrective measures undertaken by your company or the supporting documents associated with those corrective and preventive actions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Exportability will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at (949) 798-7649.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Sincerely,

Alonza E. Cruse
District Director
Los Angeles District Office

Cc: State Department of Public Health
Environmental Health Services
Attn: Chief, Food and Drug Branch
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Sacramento, CA 94234-7320